K120064

510(k) Summary

SEP 5 2012

1. Submitter Information

Company name:	HMD BioMedical Inc.
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Date Prepared:	August 7, 2012

2. Name of Device

Trade/Proprietary Name:

PRECICHEK Cloudia Blood Glucose Monitoring System

Common name:	Blood Glucose Test System
Classification name:	Glucose Test System
Classification Panel:	Clinical Chemistry (75)
Regulation no.:	862.1345 (Class II), 862.1660 (Class I)
Product code:	NBW, LFR, JJX

3. Predicate Device

Trade/Proprietary name:	Telcare Blood Glucose Monitoring System
Common name:	Blood Glucose Test System
Submitter:	Telcare, Inc.
510(k) no.:	K110571
Product code:	CGA, NBW, JJX, JQP

Common name:	Glucose Control Solution
Submitter:	HMD BioMedical, Inc.
510(k) no.:	K032985
Product code:	JJX

4. Device Description

PRECICHEK Cloudia Blood Glucose Monitoring System consists of:

(1) Glucose Meter

(2) Glucose Test Strips

(3) Two levels of glucose control solutions (Level I and Level II) may be purchased separately. Glucose control solutions were previously cleared under K032985.

(4) Check Strip

(5) Instruction for use

[Test Principle]

PRECICHEK Cloudia Blood Glucose Monitoring System is an electrochemical biosensor system that measures the amount of electric current produced then displays the result as a blood glucose level on the LCD monitor. When the blood is drawn into the blood reaction zone of the test strip, the glucose in the blood sample mixes with a special chemical in the test strip, which produces a small electric current. The reaction current is proportional to the amount of glucose in the blood. The result is displayed on the LCD monitor and automatically stored in the meter for future use.

[Control Solution]

The PRECICHEK Glucose control solution is intended for in vitro diagnostic use (i.e. for external use only) assessing the performance of the PRECICHEK Cloudia Blood Glucose monitoring system and PRECICHEK ACH Blood Glucose Test strips. There are two levels of controls (Levels 1,2).

[Check Strip]

The Check Strip can be used to check that the meter is operating properly. It is composed of PCB, resistor, top cover and bottom cover.

[Device Calibration]

The device is calibrated by implicit coding process. While inserting the test strip into strip slot to perform the blood glucose test, the coding procedure is complete. The meter will apply formula including this parameter of code to calculate the glucose value.

5. Intended Use

The PRECICHEK Cloudia Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The PRECICHEK Cloudia Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The PRECICHEK Cloudia Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The PRECICHEK Cloudia Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The PRECICHEK ACH Blood Glucose Test Strips are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The PRECICHEK Glucose Control Solutions are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System and PRECICHEK ACH Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

6. Comparison of Subject Devices and predicate device

Technological Characteristics Comparison Table of PRECICHEK Cloudia Blood Glucose Monitoring System and Telcare Blood Glucose Monitoring System (K110571)

Item	**Subject Device** PRECICHEK Cloudia BGMS	**Predicate Device** Telcare BGMS
Similarities		
Intended use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood	Same
Detection method	Amperometry: Current produced by chemical reaction	Same
Test range	20~600mg/dL	Same
Operating conditions	50~104°F (10~40°C), 20~80%	Same
Autocoding	Yes	Same
Differences		
Enzyme	Glucose Dehydrogenase (FAD) (Aspergillus oryzae)	Glucose Oxidase
Capillary testing site	Fingertips only	Alternate site testing
Sample volume	0.5ul	0.8ul
Memory	999	300
Average	7, 14, 21, 28 days	7, 14, 30 days
Test time	5 sec	6 sec
data transmission	N/A	GSM

7. Discussion of Clinical Tests Performed

PRECICHEK Cloudia Blood Glucose Monitoring System (Subject Device) is compliant to the standard of ISO 15197:2003 In vitro diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus. All the relevant activities were performed by professionals and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

   The subject device was tested to evaluate its safety and effectiveness, including the followings:

   (1) ISO 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

   (2) IEC/EN 60601-1:2005 + CORR. 1(2006) + CORR. 2(2007), EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

   (3) IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility- Requirements and tests

   (4) CLSI/NCCLS EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods

   (5) CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement.

   (6) CLSI EP07-A2: Interference Testing in Clinical Chemistry

   (7) CLSI/NCCLS EP09-A2: Method Comparison and Bias Estimation Using Patient Samples

   (8) FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

9. Conclusion

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

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SEP 5 2012

Re: k120064
Trade Name: PreciChek Cloudia Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: August 24, 2012
Received: August 28, 2012

Dear Ms Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120064

Device Name [Trade Name]:

PRECICHEK Cloudia Blood Glucose Monitoring System

Indications for Use:

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The PRECICHEK Cloudia Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The PRECICHEK Cloudia Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The PRECICHEK ACH Blood Glucose Test Strips are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The PRECICHEK Glucose Control Solutions are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System and PRECICHEK ACH Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use _____ AND/OR Over-The-Counter Use V

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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